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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 06/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/926,496	Applicant(s) MCNEIGHT, DAVID LESLIE	
	Examiner Isis Ghali	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) 1-16 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-16 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The receipt is acknowledged of applicant's preliminary amendment, and small entity refund, both filed 01/25/2002; and IDS, filed 02/25/2002.

Specification

1. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
(e) BACKGROUND OF THE INVENTION.
(1) Field of the Invention.
(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(f) BRIEF SUMMARY OF THE INVENTION.
(g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(h) DETAILED DESCRIPTION OF THE INVENTION.
(i) CLAIM OR CLAIMS (commencing on a separate sheet).
(j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).

(k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

2. The specification is replete with phrases which are not clear, concise and exact. Examples of some unclear, inexact or verbose terms used in the specification are: in page 2, second paragraph, lines 3-4, the following phrase: "there is disposal problem involved with gum which by and large its users ignore", and the examiner suggests: "there is disposal problem involved with gum which its users ignore". In page 4, the forth paragraph starts with the phrase "The thus", and the examiner suggests to remove the word "thus". In page 4, fifth paragraph states that: "Thus will a desired concentration of nicotine encapsulated in yeast cells be obtained." and the examiner suggests to rephrase it as: "Thus, a desired concentration of nicotine encapsulated in yeast cells will be obtained." In page 5, forth line of the third paragraph, the word "dose" is misspelled as "does".

Drawings

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 21, 22, 31, and 32 (page 5, first and second paragraphs of the specification). A proposed drawing correction or corrected drawings are required in

reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Minor Informalities

4. Claim 4 appears to miss the operator "and" before the phrase "empty cells*". For examination purpose, the claim is interpreted as the delivery system comprises mixture of empty cells and cells charged with diluted nicotine.*

Claim Objections

5. Claim 2 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 2 fails to limit the delivery system recited in claim 1 *per se* that comprises encapsulated nicotine in microcapsule. The claim limits the solvent that is recited as part of the intended mechanism of action upon use of the delivery device of claim 1, and not a part of the delivery system *per se*.

6. Claim 13 is objected to because of the following informalities: the claim depends on claim 23 that does not exist. Thus, it appears to the examiner that it is a typographical error. Appropriate correction is required. *In order to expedite the*

prosecution and for examination purpose, claim 13 is treated as to depend on claim 12 because it appears that claim 13 limits the flavoring substance of claim 12.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1, 2, 5, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by GB 2171906 ('906).

Claims 1, 2, 5 and 16 read as delivery system for nicotine comprising encapsulated nicotine, the delivery system is in a solid form or a patch.

GB '906 disclosed a controlled release composition of active agents include nicotine provided in controlled release transdermal or oral devices, such devices read on the solid carrier of claim 5 and the patch of claim 16 (abstract; page 2, lines 69-75; page 5, lines 8-11, 18-19). The active agent is contained in plurality of microcapsules that distributed throughout the delivery device, and delivered continuously from the

microcapsules to the skin or mucosa (page 2, lines 83-94). The active agent, i.e. nicotine, is administered from a suitable device in any convenient and appropriate form (page 3, lines 3-5). The solid active agent is delivered with a solvent, i.e. diluent (page 3, lines 5-10). The release of the active agent upon contact of the microcapsules with a nicotine solvent, as well as the limitation of claim 2 are related to the intended mechanism of action upon use of the delivery system, and not to the delivery system *per se,* and the mechanism of action of the encapsulated nicotine is inherent in the encapsulated nicotine of the prior art.

Thus, the limitations of claims 1, 2, 5, and 16 are met by GB '906.

9. Claims 1, 2, and 5 are rejected as being anticipated by US 5,824,334 ('334) under both of 35 U.S.C. 102(a) with the effective date is the issue date of October 20, 1998; and under 35 U.S.C. 102 (e) with the effective date is the filing date of April 19,1996

US '334 disclosed a nicotine containing dosage form for controlled release of nicotine comprising microencapsulated nicotine within a barrier capable of releasing the nicotine for transmucosal administration, the barrier reads on the solid carrier of claim 5 (abstract; col.9, lines 37-45; col.10, lines 8-10). The release of the active agent upon contact of the microcapsules with a nicotine solvent, as well as the limitation of claim 2 are related to the intended mechanism of action upon use of the delivery system, and not to the delivery system *per se,* and the mechanism of action of the encapsulated nicotine is inherent in the encapsulated nicotine of the prior art.

Thus, the limitations of claims 1, 2, and 5 are met by US '334.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB '906 in view of US 5,830,463 ('463).

claims 3 and 4 recite the microcapsules comprise yeast cells.

GB '906 disclosed a controlled release composition of active agents include nicotine provided in controlled release transdermal or oral devices, such devices read on the solid carrier of claim 5 and the patch of claim 16 (abstract; page 2, lines 69-75; page 5, lines 8-11, 18-19). The active agent is contained in plurality of microcapsules that distributed throughout the delivery device, and delivered continuously from the microcapsules to the skin or mucosa (page 2, lines 83-94). The active agent, i.e. nicotine, is administered from a suitable device in any convenient and appropriate form (page 3, lines 3-5). The solid active agent is delivered with a solvent, i.e. diluent (page 3, lines 5-10).

GB '906, however, does not teach that the microcapsules comprise yeast cells as claimed in claims 3 and 4.

US '463 teaches yeast vehicle used for drug delivery (abstract). The yeast cells are safe and do not cause significant side effects (col.4, line 57; col.5, lines 35-36). The yeast vehicle carries the drug within the yeast periplasm, i.e. the drug inside the yeast cell that encapsulates the drug, or the yeast cell carries the drug on the membrane, i.e. the yeast cell itself is empty, and combination thereof (col.5, lines 1-4; col.6, lines 14-36). The yeast delivery vehicle is used for solid oral or transdermal controlled release formulations (col.18, lines 5-6, 24-25, 54-55, 63-66; col.19, lines 1-3).

Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to obtain a controlled release delivery system comprising encapsulated nicotine as taught by GB '906, and replace microcapsules that encapsulate the nicotine and the solvent by the yeast cells as taught by US '463, motivated by the teaching of US '463 that the yeast cells are safe and do not cause significant side effects, with reasonable expectation of having a delivery system comprising encapsulated nicotine with the capsules comprising yeast cells that deliver nicotine safely at controlled release rate to the subject in need with minimal side effects.

12. Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '334 in view of US '463.

Claims 3 and 4 recite the microcapsules comprise yeast cells.

US '334 disclosed a nicotine containing dosage form for the controlled release of nicotine comprising microencapsulated nicotine within a barrier capable of releasing the nicotine for transmucosal administration, the barrier reads on the solid carrier of claim 5

(abstract; col.9, lines 37-45; col.10, lines 8-10). The reference further teaches the core of the capsule comprises both nicotine and other excipients, that read on diluent of claim 4 (col.14, lines 47-54).

US '334, however, the does not teach that the microcapsules comprises yeast cells as claimed in claims 3 and 4.

US '463 teaches yeast vehicle used for drug delivery (abstract). The yeast cells are safe and do not cause significant side effects (col.4, line 57; col.5, lines 35-36). The yeast vehicle carries the drug within the yeast periplasm, i.e. the drug inside the yeast cell that encapsulates the drug, or the yeast cell carries the drug on the membrane, i.e. the yeast cell itself is empty, and combination thereof (col.5, lines 1-4; col.6, lines 14-36). The yeast delivery vehicle is used for solid oral or transdermal controlled release formulations (col.18, lines 5-6, 24-25, 54-55, 63-66; col.19, lines 1-3).

Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to obtain a controlled release delivery system comprising encapsulated nicotine as taught by US '334, and replace the encapsulating material that encapsulate nicotine and the excipient by the yeast cells as taught by US '463, motivated by the teaching of US '463 that the yeast cells are safe and do not cause significant side effects, with reasonable expectation of having a delivery system comprising encapsulated nicotine with the capsules comprising yeast cells that deliver nicotine safely at controlled release rate to the subject in need with minimal side effects.

13. Claims 6-9, 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB '906 in view of US 5,733,574 ('574).

Claims 6-9 recite the delivery system as lozenge comprising sugar; and the delivery system further comprising flavoring agent (claim 12) and vitamin (claim 14), and claims 13 and 15 recite that the flavoring agent and the vitamin are encapsulated.

GB '906 disclosed a controlled release composition of active agents include nicotine provided in controlled release transdermal or oral devices, such devices read on the solid carrier of claim 5 and the patch of claim 16 (abstract; page 2, lines 69-75; page 5, lines 8-11, 18-19). The active agent is contained in plurality of microcapsules that distributed throughout the delivery device, and delivered continuously from the microcapsules to the skin or mucosa (page 2, lines 83-94). The active agent, i.e. nicotine, is administered from a suitable device in any convenient and appropriate form (page 3, lines 3-5). The solid active agent is delivered with a solvent, i.e. diluent (page 3, lines 5-10).

GB '906 does not teach the delivery system as a lozenge comprising sugar as claimed in claims 6-9, or the delivery system comprises flavoring agent and supplemental vitamin or the encapsulation of the flavoring agent and the vitamin as claimed in claims 12-15.

US '574 teaches a saliva soluble delivery unit for oral use that provides a controlled release of nicotine in the form of lozenge (abstract; col.3, lines 10-16; col.9, lines 34-35, 44, 48). The saliva soluble delivery unites comprising nicotine, sugar, flavoring agent, and vitamins because smokers usually loose vitamins and some

vitamins act as stabilizing agents (col.7, lines 58-62; col.8, lines 31-34, 51-64). The reference teaches that the nicotine delivery unit provides a nicotine dose corresponding to the stimulation of nicotine obtained by smoking a cigarette (col.3, lines 30-34; col.5, lines 31-33). The reference also disclosed that the flavor could be tobacco flavor that is provided from smokeless nicotine and does not contribute significantly to the level of nicotine (col.3, lines 34-36; col.8, lines 31-34).

One having ordinary skill in the art would have encapsulate the flavoring agents and the vitamins for the same reason the active ingredient has been capsulated by GB '906, i.e. providing continuous controlled release of the encapsulated agents.

In order to have the delivery of nicotine that provide a particular blood concentration in a certain period of time, one having ordinary skill in the art would have been expected to adjust the oral delivery unit regarding its size, solubility and charge of nicotine to obtain the desired blood concentration in the desired time. Applicant is not claiming any particular amount of nicotine in the cigarette nor the desired blood level that needed to be achieved.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to obtain a controlled release delivery system comprising encapsulated nicotine as taught by GB '906 in the form of lozenge that comprises sugar vitamins and flavoring agent as disclosed by US '574, motivated by the teaching of US '574 that the delivery units in form of lozenge provide nicotine dose corresponding to the stimulation of nicotine obtained by smoking a cigarette, as desired by applicant, and also one having ordinary skill in the art would have been motivated to

add flavoring agent and vitamin to the nicotine lozenge motivated by the teachings of US '574 that the flavor could be tobacco flavor that is provided from smokeless nicotine and does not contribute significantly to the level of nicotine and that smokers usually loose vitamins and some vitamins act as stabilizing agents, with reasonable expectation of having a lozenge that provides nicotine equivalent to that delivered by cigarette in a controlled release manner and meanwhile deliver vitamin supplement all in one delivery system that have an acceptable flavor.

14. Claims 6, 7, 9, 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB '906 in view of US 6,358,060 ('060).

Claims 6, 7, and 9 recite the delivery system as a lozenge, and claim 11 recites the delivery system as chewing gum.

GB '906 disclosed a controlled release composition of active agents include nicotine provided in controlled release transdermal or oral devices, such devices read on the solid carrier of claim 5 and the patch of claim 16 (abstract; page 2, lines 69-75; page 5, lines 8-11, 18-19). The active agent is contained in plurality of microcapsules that distributed throughout the delivery device, and delivered continuously from the microcapsules to the skin or mucosa (page 2, lines 83-94). The active agent, i.e. nicotine, is administered from a suitable device in any convenient and appropriate form (page 3, lines 3-5). The solid active agent is delivered with a solvent, i.e. diluent (page 3, lines 5-10).

GB '906 does not each the delivery system as a lozenge as claimed in claims 6, 7, and 9 or chewing gum as claimed in claim 11.

US '060 teaches a delivery system in the form of lozenge or chewing gum to deliver encapsulated nicotine, wherein the delivery system is convenient, reliable, practical and painless (abstract; col.7, lines 10-12, 56-59; col.10, lines 46-47). The delivery system provides amount of nicotine that is absorbed into the blood stream within 5 minutes and provides concentration sufficient to provide craving relief and for 20 minutes (col.8, lines 2-10; col.9, lines 49-61).

In order to have the delivery of nicotine that provide a particular blood concentration in a certain period of time, one having ordinary skill in the art would have been expected to adjust the oral delivery unit regarding its size, solubility and charge of nicotine to obtain the desired blood concentration in the desired time. Applicant is not claiming any particular amount of nicotine in the cigarette nor the desired blood level that needed to be achieved.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide the nicotine oral delivery system of GB '906 in the form of lozenge or chewing gum as disclosed by US '060, motivated by the teaching of US '060 that lozenge and chewing gum are convenient, reliable, practical and painless method to administer nicotine, and lozenge and chewing gums provide amount of nicotine that is absorbed into the blood stream within 5 minutes and provides concentration sufficient to provide craving relief and for 20 minutes, with reasonable

expectation of having a lozenge or chewing gum to deliver nicotine in a controlled release manner and also provide craving relief for sufficient time to the subject in need.

15. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over GB '906 in view of US '574 as applied to claims 6-9, 12-15 above or over GB '906 in view of US '060 as applied to claims 6,7, 9, and 11 above, and further in view of GB 2 299 756 ('756).

Claim 10 recites the lozenge having 5-20 cm length with preferential snapping positions.

The teachings of GB '906 in view of US '574 and GB '906 in view of US '060 are discussed above. However, the references in combination do not teach the size or shape of the lozenge delivery system.

GB '756 teaches product in the form of pastille for oral ingestion containing nicotine and flavoring agent, vitamin, and sugar (abstract; page 1, last paragraph; claims 5, 6, 9, 16, 17). The pastille may be of such size and contain as much nicotine as will correspond to the time taken to smoke a cigarette and the amount of nicotine absorbed by the tissue of the buccal cavity during such time (page 3, second full paragraph). The product in the form of rod or bar-like and has zones of weakness allowing it to be broken into smaller pieces, claim 10 (page 3, second full paragraph; claim 14).

The reference implies that the size of the delivery unit is adjustable to such size and contain as much nicotine as will correspond to the time taken to smoke a cigarette

and the amount of nicotine absorbed by the tissue of the buccal cavity during such time. Thus, the size of the lozenge as a whole as claimed by applicant does not impart patentability to the claim because what is important is the size and amount of the nicotine in the snapped part that administer the nicotine, and also we do not know how much nicotine in the claimed size or how much blood concentration needed to be achieved, absent evident to the contrary.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver the delivery system in the form of lozenge as taught by GB '906 in view of any of US '574 or US '060 and select the bar-like shape with zones of weakness to break the lozenge as taught by GB '756, motivated by the teaching of GB '756 that the breakable system ease the accommodation in the mouth while providing the requisite dosage of nicotine over the appropriate time, with reasonable expectation of providing lozenge with preferential snapping positions that accommodate in the mouth and provide the sufficient nicotine level in the blood for the required period of time as a successful smoking substitute.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (703) 305-4048. The examiner can normally be reached on Monday through Thursday from 7:00 AM to 5:30 PM, Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached on (703) 308-2927. The fax phone

number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Isis Ghali
Examiner
Art Unit 1615

Isis Ghali